Paper No. 47

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID WALLACH,
HARTMUT ENGELMANN,
DAN ADERKA,
DANIELA NOVICK, and
MENACHEM RUBINSTEIN

Appeal No. 2002-1363
Application No. 08/485,129

HEARD: November 21, 2002

Before WINTERS, ADAMS, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 11 through 13, 35 through 38, 43, 44, 46 through 49, 51 through 54, 56 through 61, 63, and 64. Claims 14, 39, 45, 50, 55, and 62, which are the only other claims remaining in the

application, stand withdrawn from further consideration by the examiner as directed to a non-elected invention.

The Invention

The invention relates to isolated DNA molecules which encode Tumor Necrosis Factor Binding Protein II (TBP-II). Claim 11, which is illustrative of the subject matter on appeal, reads as follows:

> 11. An isolated DNA molecule comprising a contiguous nucleotide sequence coding for a protein consisting of naturally occurring human Tumor Necrosis Factor (TNF) Binding Protein II, herein designated TBP-II, said TBP-II including the amino acid sequence: Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr in the portion of the protein sequenced by N-terminal sequence analysis, said protein having the ability to inhibit the cytotoxic effect of TNF, wherein said naturally occurring TBP-II protein is the same as that protein having the ability to inhibit the cytotoxic effect of TNF which, after being purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized TNF, elutes from a reversed-phase high pressure liquid chromatography column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 30 kDa when measured by SDS-PAGE under reducing conditions.

The Rejections

In rejecting all of the appealed claims, the examiner does not rely on any prior art references.

Claims 11 through 13, 35 through 38, 43, 44, 46 through 49, 51 through 54, 56 through 61, 63, and 64 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a specification which does not provide an adequate written description of the claimed invention (Paper No. 41, section (10) A). As formatted in the Examiner's

Answer, claims 35 through 38, 43, 44, 46 through 49, and 51 also stand rejected under 35 U.S.C. § 112, first paragraph, on the same ground, i.e., as based on a specification which does not provide an adequate written description of the claimed invention (Paper No. 41, section (10) B). In a sense, the latter "rejection" is subsumed by the former because claims 35 through 38, 43, 44, 46 through 49, and 51 are included in the former rejection based on the same statutory provision. Be that as it may, by entering the latter rejection, the examiner focuses attention on those claims which "read on" a contiguous nucleotide sequence coding for a specified fragment of TBP-II. The examiner offers additional reasons why those claims lack adequate, written descriptive support in the original specification.

In view of our disposition of this appeal, for reasons discussed more fully infra, we find it unnecessary to discuss the separate "rejection" of claims 35 through 38, 43, 44, 46 through 49, and 51 (Paper No. 41, section (10) B). Rather, we confine our discussion to the examiner's rejection of all the appealed claims under 35 U.S.C. § 112, first paragraph, based on a failure to comply with the written description requirement (Paper No. 41, section (10) A).

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' Appeal Brief (Paper No. 40) and the Reply Brief (Paper No. 42); and (3) the Examiner's Answer (Paper No. 41).

On consideration of the record, including the above-listed mateirals, we affirm the rejection of all the appealed claims under 35 U.S.C. § 112, first paragraph.

Discussion

We first think it prudent to clarify the administrative record with respect to Exhibits A, B, and C attached to applicants' Reply Brief (Paper No. 42). As a general rule, exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented. 37 CFR § 1.195 (2001). In this case, however, the examiner did not require a showing under the provisions of Rule 195. Rather, in Paper No. 44, mailed March 13, 2002, the examiner stated that:

> The reply brief filed 2/4/2002 has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

In our judgment, the only reasonable interpretation which these facts permit is that the examiner (1) waived the provisions of Rule 195; and (2) entered Exhibits A, B, and C, which are attached to and discussed in applicants' Reply Brief. Therefore, we have considered the Reply Brief (Paper No. 42) and the exhibits attached thereto as part of the administrative record. We note in passing that it would have been preferable for the examiner to state explicitly that Exhibits A, B, and C, attached to the Reply Brief, have been admitted and made of record.

In their Appeal Brief (Paper No. 40), page 17, applicants state that "[f]or each rejection, all of the claims grouped for that rejection stand or fall together." In deciding

this appeal, we have focused on the first stated rejection in the Examiner's Answer (Paper No. 41, section (10) A). There, the examiner argues that all of the appealed claims are based on a specification which fails to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. For the purposes of this appeal, we have selected claim 11 from the group of claims under rejection, and we shall decide the appeal on the basis of that claim alone. Accordingly, for the purposes of this appeal, we shall treat all of the appealed claims as standing or falling together with claim 11. See 37 CFR § 1.192(c)(7) (2001). On these facts, we find it unnecessary to discuss the second stated rejection in the Examiner's Answer (Paper No. 41, section (10) B).

We have carefully considered the syllogism set forth in applicants' Appeal Brief and Reply Brief. Although the syllogism is superficially appealing, nevertheless, claim 11 is drawn to genetic material; and relevant principles of law enunciated by our reviewing court require that genetic material be supported in the original specification by a written description containing a relatively high degree of specificity. That is not the case here.

It is not sufficient that applicants contemplate, in their specification, all DNA molecules coding for TBP-II. Applicants acknowledge that the specification does not contain a complete amino acid sequence of TBP-II (Appeal Brief, page 28), much less any specific nucleotide sequence coding for TBP-II. Not one species of a contiguous nucleotide sequence, supporting the genus of DNA molecules covered by claim 11, is described in the specification. Where, as here, not one species within the scope of

claim 11 is described in the specification, we find that applicants fall short of describing the genus of DNA molecules covered by claim 11.[1] Applicants' specification does not describe representative examples of DNA molecules within the genus of claim 11.

In a nutshell, claim 11 is couched in functional terms. Applicants recite an isolated DNA molecule comprising a contiguous nucleotide sequence "coding for" TBP-II. We know what the nucleotide sequence does. In their specification, however, applicants do not describe with a reasonable degree of specificity the structural makeup of even one species of DNA molecule within the scope of claim 11. The claim is generic and couched in functional terms. It is not supported by a specification which provides adequate written descriptive support, with a reasonable degree of specificity, for the claimed DNA. Stated another way, the functional description of DNA in applicants' specification is not enough to comply with the statute. A functional description of DNA does not convey to any person skilled in the art which particular DNA has been invented. Acknowledging the presence of DNA serving a particular function (encoding TBP-II) does not constitute a sufficiently specific written description of any DNA.

As stated in a similar context in Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991):

> A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other

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[1] The genus of DNA molecules covered by claim 11 includes genomic DNA, cDNA, synthetic DNA, and combinations thereof (specification, page 8).

> materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated. [citation omitted]

Referring to Amgen, but focusing on the written description requirement of 35 U.S.C. § 112, first paragraph, the court subsequently stated that:

> An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that . . . A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. Revel's argument that correspondence between the language of the count and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.
>
> As we stated in Amgen and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board [PTO Board of Patent Appeals and Interferences], one cannot describe what one has not conceived. [Fiers v. Revel, 984 F.2d 1164, 1170-1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); footnote and citation omitted]

Again, in University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), the court stated that:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. . . .
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. . . . We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us, as it was to the district court, that the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin. [footnote and citations omitted]

Applying those principles of law to the facts before us, we hold that (1) applicants do not describe the genetic material sought to be patented in claim 11 with sufficient specificity in their specification; and (2) the examiner did not err in finding that claim 11

is based on a specification which does not provide adequate, written descriptive support for the claimed subject matter.

Further, in our judgment, the recently issued opinion in Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002) is consistent with and adheres to the principles of law enunciated in Amgen, Fiers, and Eli Lilly.[2]

Conclusion

In conclusion, for the reasons set forth in the body of this opinion, we find that claim 11 is based on a specification, as filed, which does not provide adequate, written descriptive support for the claimed subject matter. Accordingly, we affirm the examiner's rejection of claim 11 under 35 U.S.C. § 112, first paragraph (written description requirement). As previously indicated, claims 12, 13, 35 through 38, 43, 44, 46 through 49, 51 through 54, 56 through 61, 63, and 64 fall together with claim 11.

The examiner's decision is affirmed.

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[2] Enzo Biochem was decided on July 15, 2002, after the briefings were filed in the case before us.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

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